

## § 1.240

(HFS-681), 5600 Fishers Lane, Rockville, MD 20857.

(7) If FDA receives a CD-ROM that does not comply with these specifications, it will return the CD-ROM to the registrant unprocessed.

(8) FDA will enter CD-ROM submissions that meet the specifications into its registration system, along with complete and legible mailed and faxed submissions, as soon as practicable, in the order FDA receives them.

(9) For each facility on the CD-ROM, FDA will mail to the preferred mailing address a copy of the cancellation(s) as entered and confirmation of the cancellation.

(10) If any information you previously submitted was incorrect at the time of submission, you must immediately resubmit your cancellation.

(11) Your registration will be considered cancelled once FDA enters your facility's cancellation data into the registration system and the system generates a confirmation.

[68 FR 58960, Oct. 10, 2003, as amended at 73 FR 15883, Mar. 26, 2008]

### ADDITIONAL PROVISIONS

#### **§ 1.240 What other registration requirements apply?**

In addition to the requirements of this subpart, you must comply with the registration regulations found in part 108 of this chapter, related to emergency permit control, and any other Federal, State, or local registration requirements that apply to your facility.

#### **§ 1.241 What are the consequences of failing to register, update, or cancel your registration?**

(a) Section 301 of the Federal Food, Drug, and Cosmetic Act prohibits the doing of certain acts or causing such acts to be done. Under section 302 of the Federal Food, Drug, and Cosmetic Act, the United States can bring a civil action in Federal court to enjoin a person who commits a prohibited act. Under section 303 of the Federal Food, Drug, and Cosmetic Act, the United States can bring a criminal action in Federal court to prosecute a person who is responsible for the commission of a prohibited act. Under section 306 of the Federal Food, Drug, and Cosmetic

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Act, FDA can seek debarment of any person who has been convicted of a felony relating to importation of food into the United States. Failure of an owner, operator, or agent in charge of a domestic or foreign facility to register its facility, to update required elements of its facility's registration, or to cancel its registration in accordance with the requirements of this subpart is a prohibited act under section 301(dd) of the Federal Food, Drug, and Cosmetic Act.

(b) FDA will cancel a registration if the agency independently verifies that the facility is no longer in business or has changed owners, and the owner, operator, or agent in charge of the facility fails to cancel the registration, or if FDA determines that the registration is for a facility that does not exist. If FDA cancels a facility's registration, FDA will mail a confirmation of the cancellation to the facility at the address provided in the facility's registration.

(c) If an article of food is imported or offered for import into the United States and a foreign facility that manufactured/processed, packed, or held that article of food has not registered in accordance with this subpart, the disposition of the article of food shall be governed by the procedures set out in subpart I of this part.

[68 FR 58960, Oct. 10, 2003, as amended at 80 FR 56143, Sept. 17, 2015]

#### **§ 1.242 What does assignment of a registration number mean?**

Assignment of a registration number to a facility means that the facility is registered with FDA. Assignment of a registration number does not in any way convey FDA's approval or endorsement of a facility or its products.

#### **§ 1.243 Is food registration information available to the public?**

(a) The list of registered facilities and registration documents submitted under this subpart are not subject to disclosure under 5 U.S.C. 552 (the Freedom of Information Act). In addition, any information derived from such list or registration documents that would disclose the identity or location of a